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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Taka Aki Sato
Serial No.: 09/809,920 Examiner: Mary Schmidt
Filed : March 16, 2001 Group Art Unit: 1635
For : TREX, A NOVEL GENE OF TRAF-INTERACTING EXT GENE
FAMILY AND DIAGNOSTIC AND THERAPEUTIC USES
THEREOF

1185 Avenue of the Americas
New York, NY 10036

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

DECLARATION UNDER 37 C.F.R. §1.131

I, Taka Aki Sato, hereby declare that:

1. I am the sole inventor of the subject matter encompassed by the claims of the above-identified application as amended by the Amendment submitted herewith (the "claimed invention").
2. The claimed invention encompasses, and is exemplified by, an isolated nucleic acid encoding a mammalian Tumor necrosis factor Receptor-Associated Factor ("TRAF") protein-interacting hereditary multiple extoses ("TREX") protein (the "claimed nucleic acid").
3. I have read the Office Action issued on November 22, 2002 by the United States Patent and Trademark Office in connection with the subject application. I understand that in the Office Action, certain claims of the subject application encompassing the claimed nucleic acid have

been rejected as allegedly anticipated by GenEmbl AF001690 (dated February 20, 1998), Van Hul et al., *Genomics* 47(2), 230-237 (dated January 15, 1998), and GenEmbl AB011091 (dated April 10, 1998).

4. The claimed nucleic acid was conceived solely by me in the United States prior to January 15, 1998.
5. In accordance with my conception of the claimed nucleic acid, experiments were conducted either directly by me, or by others under my direction and supervision, to reduce the claimed nucleic acid to practice in the United States prior to January 15, 1998.
6. Specifically, detailed below in paragraphs 7-9 are experiments which I and/or those working under my direction and supervision performed in the United States prior to January 15, 1998 to isolate nucleic acid encoding the protein designated "CAP-2" and later renamed "TREX" protein.
7. To isolate cells comprising CAP-2-encoding nucleic acid, I and/or those working under my direction and supervision performed a yeast two hybrid screening experiment. This experiment employed yeast L40 strain cells containing two types of plasmids. The first type of plasmid was designated "pBTM116" and contained a human TRAF-3-encoding sequence. The second type of plasmid was designated "pVP16" and contained a portion of a mouse embryo cDNA library. This screening experiment resulted in the isolation of cells comprising mouse CAP-2-encoding nucleic acid in the form of cDNA. As evidence of the

performance of this screening experiment, I attach hereto as **Exhibit 1** a copy of pages 7-9 from the laboratory notebook of Dr. Junn Yanagisawa who, at the time of this experiment, was a post-doctoral fellow in my laboratory working under my direction and supervision. It is noted that annexed pages 7-9 in fact constitute six pages, in that there exist two separate notebook pages designated "007", two separate notebook pages designated "008" and two separate notebook pages designated "009."

8. I and/or those working under my direction and supervision isolated cDNA encoding a portion of mouse CAP-2 ("mouse cDNA") from the cells isolated in the screening experiment described in paragraph 7 above. I and/or those working under my direction and supervision then determined the sequence of the isolated mouse cDNA. As evidence of the isolation and sequencing of the mouse cDNA, I attach hereto as **Exhibit 2** a copy of an annotated document setting forth the nucleic acid sequence of the mouse cDNA and the amino acid sequence encoded thereby.
9. I and/or those working under my direction and supervision employed the mouse cDNA isolated in the experiment described in paragraph 8 above to isolate a cDNA encoding a full-length human CAP-2 protein ("human cDNA"). I and/or those working under my direction and supervision then determined the nucleic acid sequence of the isolated human cDNA. As evidence of the isolation and sequencing of the human cDNA, I attach hereto as **Exhibit 3** a copy of an annotated document setting forth the nucleic acid sequence of the isolated human cDNA, as well as the amino

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acid sequences encoded by each of the three reading frames thereof.

10. All copies submitted as Exhibits 1-3 are true and accurate copies of the original documents, except that any dates which appear on the original documents have been redacted. All redacted dates are prior to January 15, 1998.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such willful false statements may jeopardize the validity of this application or any patent issued thereon.

April 22nd/2003

Date

Taka Aki Sato

Taka Aki Sato, Ph.D.